

K963044

SEP 20 1996

(g) Detailed Similarities/Differences Comparison:

Endospot 510(k) Device

Power Source

On/Off Button

Manual Illumination Control

Automatic Illumination Control

UV/IR Filters

35 Watt

Xenon Microdischarge Lamp

1 Lamp in Unit

Stepless Light Intensity Adjustment

4000 Lamp Hours

Autobrite (Predicate Device)

Power Source

On/Off Button

Manual Illumination Control

Automatic Illumination Control

UV/IR Filters

100 Watt

Xenon Lamp Module

1 Lamp in Unit

Stepless Light Intensity Adjustment

1000 Lamp Hours

8. 510(k) Summary:

Classification Name:

Accessory to Endoscope

Device Trade Name:

Endobeam

Sponsor:

Corin U.S.A.
 10500 University Center Drive
 Suite 130
 Tampa, FL 33612
 USA

Reason for Submission:

New device

Intended Use:

Endoscopic light source to provide
 illumination for fibre optic endoscopy to
 joint cavities and abdominal space.

Major Components:

- Power Source
 - Xenon Microdischarge Lamp

Lamp/Data

- Light intensity 35W
 - Lamp life - 4000 hours
 - Color temperature - 3700K

Power Source:

100 - 240V \pm 10% 0 - 440 Hz

Safety Testing:

- TUV tested to IEC 601/1 1988
 - DIN VDE 0750 TI/11.91
 - Electromagnetic compatibility
 tested

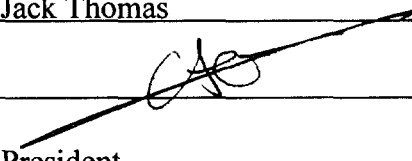
Comparison to Legally Marketed Endoscopic Light Source:

Dyobrite 3000 Xenon Illuminator
Smith and Nephew Dyonics
160 Dascomb Road
Andover, Massachusetts 01810
USA

9. **Truthful and Accurate Statement:**

I hereby confirm that the attached information is, to the best of my knowledge, truthful and accurate.

PRINT NAME: Jack Thomas

SIGNED: 

POSITION: President

DATE: 1 August 1996